(b) detecting whether immunospecific binding has occurred between the polypeptide and an antibody component of the body fluid in which an immune complex is formed and in which detection of the immune complex indicates the presence of antibodies to HIV in the body fluid.

REMARKS

Claims 1-14 and 16-25 are currently pending in the above-identified application. Claims 13, 14, and 16-25 have been withdrawn from consideration by the Examiner as being directed to a non-elected invention. Claims 1-12 have been examined. By this amendment, claims 1, 12, and 13 have been amended to set forth the invention with greater particularity and to further expedite prosecution of the instant application as set forth in detail below. All amendments are fully supported by the specification. No new matter has been added by these amendments.

Claims 1, 12, and 13 have been amended to correct certain typographical and grammatical errors. In claims 1, 12, and 13, the phrase "contacting under conditions which permit immunospecific binding to form a reaction mixture the body fluid with ..." has been amended by inserting commas following the terms "contacting" and "reaction mixture." In addition, due to the inadvertent insertion of a period followed by language previously recited in claim 1, the claim has been amended to remove both the period immediately following the first recitation of the phrase "Z is OH or NH_2" as well as the redundant language immediately following such period and preceding "(b)." Also, claims 1, 12, and 13 have been amended to insert the term "and" immediately preceding recitation of step "(b)." Because these amendments merely delete redundant language and correct minor typographical errors, Applicants believe these amendments are not narrowing.

To avoid redundancies in terminology and conform such terminology to that used throughout the dependent claims, the phrase "at least one polypeptide or protein" in claims 1, 12, and 13 has also been amended to recite "at least one

polypeptide," thereby removing the term "protein." As indicated, Applicants believe the term "protein" as used in the claim to be synonymous with the term "polypeptide" and, thus, redundant. Therefore, Applicants do not believe this amendment to be narrowing.

In addition, again to avoid redundant language, claim 13 has been amended by substituting the phrase "... comprising the following amino acid sequences where oligopeptides having at least six amino acids which come within the sequence of at least one of the following polypeptide sequences ..." with the phrase "... comprising at least six amino acids which come within at least one of the following polypeptide sequences ...." As indicated, Applicants believe the deleted language to be repetitive and unnecessary and thus believe the claim as amended to have the same meaning as the original claim. Therefore, Applicants believe that this amendment is not narrowing.

In view of the amendment to claim 13 set forth immediately above, the term "... will include epitopes within such sequence" has been amended to recite "... and including epitopes within such sequence" in order to conform to correct grammatical form. Because the amendment relates to grammatical form, Applicants believe that this amendment is not narrowing.

In claim 12, the term "detecting" has been substituted for the term "determining" to conform to the terminology used in claim 1. Because Applicants believe these terms to be synonymous as used in the specification and claims, Applicants believe that this amendment is not narrowing.

Further, in claims 12 and 13, to further clarify the claimed invention and to conform the terminology of the claims to that in claim 1, the phrase "body fluid in which detection of immunospecific binding indicates the presence of antibodies to HIV ..." has been amended to recite "body fluid in which an immune complex is formed and in which detection of the immune complex indicates the presence of antibodies to HIV ...." Applicants believe that the amended phrase merely clarifies that which would be understood by the skilled artisan upon reading claims 12 and 13 in light of the specification and as already recited in claim 1. Therefore, Applicants believe that these amendments are not narrowing.

To further expedite prosecution of the instant application, Applicants have amended claims 1 and 12 to cancel certain subject matter. Claims 1 and 12, which as unamended recite "... polypeptide ... comprising the following amino acid sequences where oligopeptides having at least six amino acids which come within the sequence of at least one of the following polypeptide sequences will include epitopes within such sequence ...," to recite "... polypeptide comprising at least one of the following polypeptide sequences ...."

The Examiner has acknowledged Applicants' submission of missing pages 24 and 25 of the specification. The Examiner has stated that entry of these pages into the specification will be considered upon submission of a copy of the receipt postcard confirming Applicants' original filing of these pages. Applicants are providing attached to this response a copy of the receipt postcard and respectfully request that the Examiner enter the pages into the specification.

The Examiner has objected to the application because of alleged "alterations which have not been initialed and/or dated as is required by 37 C.F.R. 1.52(c) and 1.56." The Examiner has stated that a "properly executed oath or declaration which complies with 37 CFR 1.67(a) is required ...." Applicants have reviewed the specification as filed in comparison to the parent application and have noted that extraneous marks may have appeared during copying. Applicants have enclosed with this response a substitute specification (see below), which corresponds with the text of the parent application as filed and does not contain these extraneous marks. The Examiner's objection is believed to be obviated. A new executed oath and declaration will be submitted if the Examiner believes it to be required.

The Examiner has objected to the specification because he believes it fails to comply with the Sequence Rules. In particular, sequence identifiers were to be added to the specification. In accordance with the Examiner's request, Applicants submit herewith a substitute specification with the required sequence identification numbers. Applicants have also corrected minor typographical errors in the specification. Applicants

also enclose a marked up version of the specification showing the changes. No new matter is believed to be added by these changes.

The Examiner has also requested a new copy of the CRF sequence listing, as the originally submitted diskette was damaged and could not be read. Applicants submit herewith a new CRF sequence diskette with a paper copy. Pursuant to 37 CFR §1.821(f) and (g), it is believed that the content of the paper sequence listing and the computer readable sequence listing are the same. Further, the present submission of the printed pages and computer disk are not believed to constitute new matter.

Rejections Under 35 U.S.C. § 112, Second Paragraph:

Claims 1-11 stand rejected under 35 U.S.C. §112, second paragraph, the Examiner believing the claims to be indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner first states that claim 1 is "indefinite in the recitation 'Z is OH or NH2.' since a claim cannot have a period in the middle of a claim." Applicants respectfully note that the rejection of claims 1-11 on this basis is mooted in view of Applicants' amendment, as set forth above, deleting the period to correct a typographical error.

The Examiner has also rejected claim 6 as allegedly vague and indefinite in the recitation of "substantially all," the Examiner believing it to be unclear "how much immunological reactivity would constitute 'substantially all.'"

Applicants respectfully traverse this rejection. Applicants first note that the determination of whether a claim is definite depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification. *See North Am. Vaccine, Inc. v. American Cyanamid Co.*, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993). It is the disclosure in the specification itself, not the technical form of the disclosure, that counts. Thus, the Examiner "should allow claims which define the patentable subject matter with a *reasonable* degree of particularity and distinctness." MPEP 2173.02 (emphasis original).

In this case, the skilled artisan, reading the claim in light of the specification, would understand the term "substantially all of the immunological reactivity," and thus the scope of the claim, with a reasonable degree of particularity. The specification relates to synthetic peptides that mimic antigenic epitopes of HIV gene products and the use of such peptides for detecting antibodies associated with HIV (*see, e.g.*, page 12, line 19, through page 15, line 7, relating antibody detection). The specification also describes the various labels that may be employed for such detection, including, *e.g.*, radionuclides, enzymes, and fluorescers (*see* page 12, line 20, bridging to page 13, line 3) and, at page 5, lines 16-19, states that "[a] polypeptide in which the amino acid sequence is modified by the substitution, addition, or deletion of amino acid residues should retain substantially all of the immunological reactivity of the unmodified peptide, which may be conveniently measured by radioimmuno-precipitation, immunofluorescence, or enzyme-linked immunosorbant assays."

Thus, in light of (1) the disclosure of polypeptides with HIV immunological reactivity; (2) the disclosed use of the polypeptides for detection of HIV-associated antibodies; and (3) disclosed methods for determining the presence of specific antibody binding to polypeptide, the skilled artisan reading the specification would understand the term "substantially all of the immunological reactivity" to mean such immunological reactivity that will allow the detection of specific binding of HIV-associated antibodies when measured by radioimmuno-precipitation, immunofluorescence, or ELISA. Therefore, claim 6 is not indefinite.

In view of the above remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 6 under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph:

Claims 1-12 are rejected under 35 U.S.C. §112, first paragraph, the Examiner believing the claims to contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention. The Examiner believes that the specification does not enable the identification or use of six amino acid sequences as claimed and further asserts that a particular epitope "varies from species to species and even within the same species" and that modification of peptides can "abrogate antigenicity." The Examiner believes that the modification of immunological peptides is "highly unpredictable" and alleges that no guidance is provided to allow the skilled artisan to identify and use such epitopes without "extensive trial and error" or "undue experimentation."

Applicants first respectfully note that the Examiner's rejection of claims 1-12 for lack of enablement is mooted with respect to claims1-5 and 7-12 by Applicants' amendment of independent claims 1 and 12 canceling certain subject matter, as set forth in the general remarks above.

With respect to claim 6, which relates to modified polypeptides, Applicants respectfully traverse this rejection. Applicants initially disagree with the Examiner's statement regarding the teachings provided by the specification and alleging that "no guidance" is provided to enable the artisan to make, identify, and use the modified polypeptides. Applicants note that the specification provides guidance for making modified polypeptides, *e.g.*, means of choosing appropriate amino acid substitutions and appropriate percentage differences from strains of HIV-1 or HIV-2 (*see, e.g.*, page 4, lines 11-20, and page 5, lines 7-13). The specification further provides guidance for identifying those polypeptides with immunological reactivity to HIV-associated antibodies: the specification discloses assays for detection of antibody binding (*see, e.g.*, pages 12-15 and the examples) and states on page 5, lines 16-19, that the immunological reactivity of modified polypeptides can be "conveniently measured by radioimmuno-precipitation, immunofluorescence, or enzyme-linked immunosorbant assays."

In addition, Applicants respectfully note that "[t]he determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the

art." *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); *see also* MPEP § 2164.08 at 2100-186 (stating that, to meet the enablement requirement, "all that is necessary is that one skilled in the art be able to practice the invention, *given the level of knowledge and skill in the art*" (emphasis added). Accordingly, predictability must be viewed in relation to other factors, including, *e.g.*, the amount of experimentation necessary, the state of the prior art, the relative skill of those in the art, and the nature of the invention. *Wands*, 8 USPQ2d at 1404. Because these other factors must be considered, any alleged unpredictability, by itself, does not presume undue experimentation.

In the present case and in view of such factors, the skilled artisan would be able to make, identify, and use the modified polypeptides as claimed with no more effort than normally required in the art. The claimed invention relates to the detection HIV-associated antibodies using synthetic peptides that mimic antigenic epitopes of HIV gene products. The specification discloses, *inter alia*, amino acid sequences that contain such antigenic epitopes and that can be used in the methods as claimed. The state of the art at the time of filing was such that epitopes within an identified antigenic region could be further localized using known methods (*see, e.g.*, Harlow & Lane, *Antibodies: A Laboratory Manual* 590 (Cold Spring Harbor Laboratory 1988), and candidate peptides could be routinely synthesized using an automated peptide synthesizer or other means. In addition, various immunochemical assays for determining immunological reactivity, such as, for example, those referred to in the specification (*see, e.g.*, page 5, lines18-19), were well-known in the art and routinely used for screening. Using such known and routine methods with the guidance provided in the specification, including, *e.g.*, the disclosed amino acid sequences containing HIV antibody epitopes, the skilled artisan would be able to make and identify modified polypeptides that contain epitopes for HIV antibodies with no more effort than normally required in the art. Thus, undue experimentation would not be required to practice the claimed invention.

Therefore, Applicants believe the full scope of claim 6 to be enabled. In view of the above remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 6 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. §102:

Claims 1-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Cosand *et al.*, EP 0 267 802 (Applicant's AE). In particular, the Examiner believes that Cosand *et al.* disclose the peptide designated (IIa)(124). The Examiner further asserts that peptide 124 is identical to the BRU124FIX peptide except that the BRU124FIX peptide is 10 amino acids longer. It is the conclusion of the Examiner that Cosand *et al.* disclose to the public that which is claimed because of the scope of the claims and the overlap between the peptides.

Applicants note that in view of amendment to claims 1 and 12 canceling certain subject matter, as set forth in the general remarks above, the Examiner's rejection under 35 U.S.C. § 102(b) is believed to be mooted.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: 23 October 2002

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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

1. (Twice Amended) A method for determining the presence of antibodies to HIV in a body fluid, comprising:

(a) contacting, under conditions which permit immunospecific binding to form a reaction mixture, the body fluid with a composition containing at least one polypeptide [or protein] comprising [the following amino acid sequences where oligopeptides having at least six amino acids which come within the sequence of] at least one of the following polypeptide sequences [will include epitopes within such sequence]:

(II) BRU124EX (SEQ ID NO: 2)

W-X-Leu-Gln-Lys-Gln-Ile-Thr-Lys-Ile-Gln-Asn-Phe-Arg-Val-Tyr-Tyr-Arg-Asp-Ser-Arg-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Y-Z

(III) BRU124F1X (SEQ ID NO: 3)

W-X-Lys-Ile-Gln-Asn-Phe-Arg-Val-Tyr-Tyr-Arg-Asp-Ser-Arg-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Val-Val-Ile-Gln-Asp-Asn-Ser-Asp-Ile-Lys-Y-Z

(IV) BRU124F3X (SEQ ID NO: 4)

W-X-Lys-Ile-Gln-Asp-Phe-Arg-Val-Tyr-Tyr-Arg-Asp-Ser-Arg-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Val-Val-Ile-Gln-Asp-Asn-Y-Z

(V) ROD 124E1 (SEQ ID NO: 5)

W-X-Lys-Leu-Lys-Asp-Phe-Arg-Val-Tyr-Phe-
Arg-Glu-Gly-Arg-Asp-Gln-Leu-Trp-Lys-Gly-
Pro-Gly-Glu-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Y-Z

(VI) ROD 124EX (SEQ ID NO: 6)

W-X-Leu-Gln-Ala-Lys-Asn-Ser-Lys-Leu-Lys-
Asp-Phe-Arg-Val-Tyr-Phe-Arg-Glu-Gly-Arg-
Asp-Gln-Leu-Trp-Lys-Gly-Pro-Gly-Glu-Leu-
Leu-Trp-Lys-Gly-Glu-Gly-Ala-Y-Z

(VII) ROD 124C2X (SEQ ID NO: 7)

W-X-Lys-Leu-Lys-Asp-Phe-Arg-
Val-Tyr-Phe-Arg-Glu-Gly-Arg-Asp-Gln-Leu-
Trp-Lys-Gly-Pro-Gly-Glu-Leu-Leu-Trp-Lys-
Gly-Glu-Gly-Ala-Val-Leu-Val-Lys-Val-Gly-
Thr-Asp-Ile-Lys-Y-Z

(VIII) ROD 124C1X (SEQ ID NO: 8)

W-X-Tyr-Phe-Arg-Glu-Gly-Arg-Asp-Gln-Leu-
Trp-Lys-Gly-Pro-Gly-Glu-Leu-Leu-Trp-Lys-
Gly-Glu-Gly-Ala-Val-Leu-Val-Lys-Val-Gly-
Thr-Asp-Ile-Lys-Y-Z

(IX) ROD 123C3X (SEQ ID NO: 9)

X-Lys-Leu-Lys-Asp-Phe-Arg-Val-Tyr-Phe-
Arg-Glu-Gly-Arg-Asp-Gln-Leu-Trp-Lys-Gly-
Pro-Gly-Glu-Leu-Leu-Trp-Lys-Gly-Glu-Gly-
Ala-Val-Leu-Val-Lys-Val-Gly-Thr-Asp-Ile-Lys-Y-Z

(X) POL2A1 (SEQ ID NO: 10)

W-X-Lys-Gly-Pro-Gly-Glu-Leu-Leu-Trp-Lys-

Gly-Glu-Gly-Ala-Val-Leu-Val-Lys-Val-Gly-
Thr-Asp-Ile-Lys-Ile-Ile-Pro-Arg-Arg-Lys-
Ala-Lys-Ile-Ile-Y-Z

(XI) ROD124C5X (SEQ ID NO: 11)

W-X-Lys-Leu-Lys-Asp-Phe-Arg-Val-Tyr-Phe-
Arg-Glu-Gly-Arg-Asp-Gln-Leu-Trp-Lys-Gly-
Pro-Gly-Glu-Leu-Leu-Trp-Lys-Gly-Glu-Gly-
Ala-Val-Leu-Val-Lys-Val-Gly-Y-Z

wherein W is either a H of the amino terminal NH_2 group of the polypeptide or an additional amino acid bonded to the amino terminal NH_2 group of the polypeptide, the additional amino acid being selected to facilitate coupling of the polypeptide to a carrier protein or to a support; X is absent or Cys-Gly-Gly; Y is absent or Cys; and Z is OH or NH_2[. wherein W is either a H of the amino terminal NH_2 group of the polypeptide or an additional amino acid bonded to the amino terminal NH_2 group of the polypeptide, the additional amino acid being selected to facilitate coupling of the polypeptide to a carrier protein or to a support; X is absent or Cys-Gly-Gly; Y is absent or Cys; and Z is OH or NH_2]; and

(b) detecting whether immunospecific binding has occurred between the polypeptide and an antibody component of the body fluid in which an immune complex is formed and in which the detection of the immune complex indicates the presence of antibodies to HIV in the body fluid.

12. (Twice Amended) A method for determining the presence of antibodies to HIV-1 in a body fluid, comprising:

(a) contacting, under conditions which permit immunospecific binding to form a reaction mixture, the body fluid with a composition containing at least one polypeptide [or protein] comprising [the following amino acid sequences where oligopeptides having at least six amino acids which come within the sequence of] at least one of the following polypeptide sequences [will include epitopes within such sequence]:

(II) BRU124EX (SEQ ID NO: 2)

W-X-Leu-Gln-Lys-Gln-Ile-Thr-Lys-Ile-Gln-Asn-Phe-Arg-Val-Tyr-Tyr-Arg-Asp-Ser-Arg-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Y-Z

(III) BRU124FX1 (SEQ ID NO: 3)

W-X-Lys-Ile-Gln-Asn-Phe-Arg-Val-Tyr-Tyr-Arg-Asp-Ser-Arg-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Val-Val-Ile-Gln-Asp-Asn-Ser-Asp-Ile-Lys-Y-Z

(IV) BRU124F3X (SEQ ID NO: 4)

W-X-Lys-Ile-Gln-Asp-Phe-Arg-Val-Tyr-Tyr-Arg-Asp-Ser-Arg-Asp-Pro-Leu-Trp-Lys-Gly-Pro-Ala-Lys-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Val-Val-Ile-Gln-Asp-Asn-Y-Z

wherein W is either a H of the amino terminal NH2 group of the polypeptide or an additional amino acid bonded to the amino terminal NH2 group of the polypeptide, the additional amino acid being selected to facilitate coupling of the polypeptide to a carrier protein or to a support; X is absent or Cys-Gly-Gly; Y is absent or Cys; and Z is OH or NH2; and

(b) [determining] detecting whether immunospecific binding has occurred between the polypeptide and an antibody component of the body fluid in which an immune complex is formed and in which the detection of [immunospecific binding] the immune complex indicates the presence of antibodies to HIV in the body fluid.

13. (Amended) A method for determining the presence of antibodies to HIV-2 in a body fluid, comprising:

(a) contacting, under conditions which permit immunospecific binding to form a reaction mixture, the body fluid with a composition containing at least one polypeptide [or protein] comprising [the following amino acid sequences where oligopeptides having] at least six amino acids which come within [the sequence of] at least one of the following polypeptide sequences [will] and includ[e]ing epitopes within such sequence:

(V) ROD 124E1 (SEQ ID NO: 5)

W-X-Lys-Leu-Lys-Asp-Phe-Arg-Val-Tyr-Phe-
Arg-Glu-Gly-Arg-Asp-Gln-Leu-Trp-Lys-Gly-
Pro-Gly-Glu-Leu-Leu-Trp-Lys-Gly-Glu-Gly-Ala-Y-Z

(VI) ROD 124EX (SEQ ID NO: 6)

W-X-Leu-Gln-Ala-Lys-Asn-Ser-Lys-Leu-Lys-
Asp-Phe-Arg-Val-Tyr-Phe-Arg-Glu-Gly-Arg-
Asp-Gln-Leu-Trp-Lys-Gly-Pro-Gly-Glu-Leu-
Leu-Trp-Lys-Gly-Glu-Gly-Ala-Y-Z

(VII) ROD 124C2X (SEQ ID NO: 7)

W-X-Lys-Leu-Lys-Asp-Phe-Arg-
Val-Tyr-Phe-Arg-Glu-Gly-Arg-Asp-Gln-Leu-
Trp-Lys-Gly-Pro-Gly-Glu-Leu-Leu-Trp-Lys-
Gly-Glu-Gly-Ala-Val-Leu-Val-Lys-Val-Gly-
Thr-Asp-Ile-Lys-Y-Z

(VIII) ROD 124C1X (SEQ ID NO: 8)

W-X-Tyr-Phe-Arg-Glu-Gly-Arg-Asp-Gln-Leu-
Trp-Lys-Gly-Pro-Gly-Glu-Leu-Leu-Trp-Lys-
Gly-Glu-Gly-Ala-Val-Leu-Val-Lys-Val-Gly-
Thr-Asp-Ile-Lys-Y-Z

(IX) ROD 123C3X (SEQ ID NO: 9)

X-Lys-Leu-Lys-Asp-Phe-Arg-Val-Tyr-Phe-
Arg-Glu-Gly-Arg-Asp-Gln-Leu-Trp-Lys-Gly-
Pro-Gly-Glu-Leu-Leu-Trp-Lys-Gly-Glu-Gly-
Ala-Val-Leu-Val-Lys-Val-Gly-Thr-Asp-Ile-Lys-Y-Z

(X) POL2A1 (SEQ ID NO: 10)

W-X-Lys-Gly-Pro-Gly-Glu-Leu-Leu-Trp-Lys-

Gly-Glu-Gly-Ala-Val-Leu-Val-Lys-Val-Gly-
Thr-Asp-Ile-Lys-Ile-Ile-Pro-Arg-Arg-Lys-
Ala-Lys-Ile-Ile-Y-Z

(XI) ROD124C5X (SEQ ID NO: 11)

W-X-Lys-Leu-Lys-Asp-Phe-Arg-Val-Tyr-Phe-
Arg-Glu-Gly-Arg-Asp-Gln-Leu-Trp-Lys-Gly-
Pro-Gly-Glu-Leu-Leu-Trp-Lys-Gly-Glu-Gly-
Ala-Val-Leu-Val-Lys-Val-Gly-Y-Z

wherein W is either a H of the amino terminal NH_2 group of the polypeptide or an additional amino acid bonded to the amino terminal NH_2 group of the polypeptide, the additional amino acid being selected to facilitate coupling of the polypeptide to a carrier protein or to a support; X is absent or Cys-Gly-Gly; Y is absent or Cys; and Z is OH or NH_2; and

(b) detecting whether immunospecific binding has occurred between the polypeptide and an antibody component of the body fluid in which an immune complex is formed and in which detection of [immunospecific binding] the immune complex indicates the presence of antibodies to HIV in the body fluid.